

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Vignia 22313-1450 www.uspto.gov

CONFIRMATION NO. ATTORNEY DOCKET NO. FIRST NAMED INVENTOR FILING DATE APPLICATION NO. 2968 1103326-283 JAN-ERIK LOFROTH 10/24/1997 08/945,655 06/24/2003 7590 1095 **EXAMINER** THOMAS HOXIE NOVARTIS, CORPORATE INTELLECTUAL PROPERTY WEBMAN, EDWARD J ONE HEALTH PLAZA 430/2 EAST HANOVER, NJ 07936-1080 PAPER NUMBER ART UNIT

> 1617 DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. Applicant(s) OS 944685 LOFR 0774 | |
|---|---|-------|
| | Examiner Group Art Unit | |
| The MAILING DATE of this communication appe | ars on the cover sheet beneath the correspondence address | - |
| Peri d for Reply | 3 | |
| OF THIS COMMUNICATION. | TO EXPIRE 3 MONTH(S) FROM THE MAILING DA | |
| from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a | 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONT reply within the statutory minimum of thirty (30) days will be considered timely. It, expire SIX (6) MONTHS from the mailing date of this communication. stute, cause the application to become ABANDONED (35 U.S.C. § 133). | |
| Status | 3/2/2 | |
| Responsive to communication(s) filed on | 3/7/03 | |
| This action is FINAL. | | |
| ☐ Since this application is in condition for allowance exce accordance with the practice under Ex parte Quayle, 1 | pt for formal matters, prosecution as to the merits is closed in 935 C.D. 1 1; 453 O.G. 213. | |
| Disp sition of Claims | -7 <i>C</i> | |
| Claim(s) | is/are pending in the application. | |
| Of the above claim(s) 3-6, 12 | is/are withdrawn from considerate | ion. |
| □ Claim(s) | is/are allowed. | |
| NClaim(s) 1-4, 15 | is/are rejected. | |
| | • | |
| ☐ Claim(s) | is/are objected to. | |
| ☐ Claim(s) | is/are objected to. are subject to restriction or elect requirement. | ion |
| ☐ Claim(s)———————————————————————————————————— | is/are objected to. are subject to restriction or elect requirement. | ion |
| ☐ Claim(s) ☐ Claim(s) ☐ Application Papers ☐ See the attached Notice of Draftsperson's Patent Draw | is/are objected to. are subject to restriction or elect requirement. | ion |
| ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) ☐ Application Papers ☐ See the attached Notice of Draftsperson's Patent Drav ☐ The proposed drawing correction, filed on | is/are objected to. are subject to restriction or elect requirement. ring Review, PTO-948. is □ approved □ disapproved. | ion |
| ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) Application Papers ☐ See the attached Notice of Draftsperson's Patent Draw ☐ The proposed drawing correction, filed on ☐ The drawing(s) filed on is/are ob | is/are objected to. are subject to restriction or elect requirement. ring Review, PTO-948. is □ approved □ disapproved. | ion |
| ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) ☐ Application Papers ☐ See the attached Notice of Draftsperson's Patent Drave ☐ The proposed drawing correction, filed on ☐ is/are ob ☐ The specification is objected to by the Examiner. | is/are objected to. are subject to restriction or elect requirement. ring Review, PTO-948. is approved disapproved. ected to by the Examiner. | ion |
| ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) Application Papers ☐ See the attached Notice of Draftsperson's Patent Draw ☐ The proposed drawing correction, filed on ☐ The drawing(s) filed on is/are ob | is/are objected to. are subject to restriction or elect requirement. ring Review, PTO-948. is approved disapproved. ected to by the Examiner. | ion |
| ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) ☐ Application Papers ☐ See the attached Notice of Draftsperson's Patent Draw ☐ The proposed drawing correction, filed on ☐ is/are ob ☐ The drawing(s) filed on ☐ is/are ob ☐ The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. ☐ Trity under 35 U.S.C. § 119 (a)-(d) | is/are objected to. are subject to restriction or elect requirement. ring Review, PTO-948. is approved disapproved. ected to by the Examiner. | ion |
| ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) ☐ See the attached Notice of Draftsperson's Patent Draw ☐ The proposed drawing correction, filed on ☐ The drawing(s) filed on ☐ The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. ☐ Pri rity under 35 U.S.C. § 119 (a)-(d) ☐ Acknowledgment is made of a claim for foreign priority ☐ All ☐ Some* ☐ None of the CERTIFIED copies ☐ received. ☐ received in Application No. (Series Code/Serial Number 1) | is/are objected to. are subject to restriction or elect requirement. ring Review, PTO-948. is approved disapproved. ected to by the Examiner. under 35 U.S.C. § 11 9(a)-(d). of the priority documents have been | ion |
| ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) ☐ Application Papers ☐ See the attached Notice of Draftsperson's Patent Draw ☐ The proposed drawing correction, filed on ☐ The drawing(s) filed on ☐ The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. ☐ Pri rity under 35 U.S.C. § 119 (a)-(d) ☐ Acknowledgment is made of a claim for foreign priority ☐ All ☐ Some* ☐ None of the CERTIFIED copies | is/are objected to. are subject to restriction or elect requirement. ring Review, PTO-948. is approved disapproved. ected to by the Examiner. under 35 U.S.C. § 11 9(a)-(d). of the priority documents have been | ion |
| ☐ Claim(s) ☐ Claim(s) ☐ Claim(s) ☐ See the attached Notice of Draftsperson's Patent Draw ☐ The proposed drawing correction, filed on ☐ The drawing(s) filed on ☐ The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. ☐ Pri rity under 35 U.S.C. § 119 (a)-(d) ☐ Acknowledgment is made of a claim for foreign priority ☐ All ☐ Some* ☐ None of the CERTIFIED copies ☐ received. ☐ received in Application No. (Series Code/Serial Number 1) | is/are objected to. are subject to restriction or elect requirement. ing Review, PTO-948. is approved disapproved. ected to by the Examiner. under 35 U.S.C. § 11 9(a)-(d). of the priority documents have been in the priority documents have been international Bureau (PCT Rule 1 7.2(a)). | ion |
| □ Claim(s) □ Claim(s) □ Claim(s) □ See the attached Notice of Draftsperson's Patent Draw □ The proposed drawing correction, filed on □ The drawing(s) filed on □ The specification is objected to by the Examiner. □ The oath or declaration is objected to by the Examiner. | is/are objected to. are subject to restriction or elect requirement. In Review, PTO-948. is approved disapproved. ected to by the Examiner. Funder 35 U.S.C. § 11 9(a)-(d). of the priority documents have been an inher. International Bureau (PCT Rule 1 7.2(a)). | ion |
| □ Claim(s) □ Claim(s) □ Claim(s) □ See the attached Notice of Draftsperson's Patent Draw □ The proposed drawing correction, filed on □ The drawing(s) filed on □ The specification is objected to by the Examiner. □ The oath or declaration is objected to by the Examiner. | is/are objected to. are subject to restriction or elect requirement. ing Review, PTO-948. is approved disapproved. ected to by the Examiner. under 35 U.S.C. § 11 9(a)-(d). of the priority documents have been inber) international Bureau (PCT Rule 1 7.2(a)). | |
| □ Claim(s) □ Claim(s) □ Claim(s) □ See the attached Notice of Draftsperson's Patent Draw □ The proposed drawing correction, filed on □ The drawing(s) filed on □ The specification is objected to by the Examiner. □ The oath or declaration is objecte | is/are objected to. are subject to restriction or elect requirement. | TO-15 |

Application/Control Number: 08/945,655

Art Unit: 1617

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Royce in view of Folkers et al.

Royce et al teach directly compressible dosage form using polyethylene oxide as a binder (abstract). Drugs without limitation are disclosed (column 4 lines 44-45).

Folkers et al disclose that fluvastatin is well-known in the art as an HMG-COA reductase inhibitor.

It would have been obvious to one of ordinary skill to deliver flue astation in the vehicle of Royce to achieve the beneficial effect of an HMG_{-CO}A reductase inhibitor in view of Folkers et al.

Applicants argue that Royce doesn't teach HMG –COA reductase inhibitors.

However, if Royce did so teach, applicants would be talking a rejection under 35 USC

102 b. Applicants argue obvious to try. However, and metivation to combine is provided.

Claims 1-4, 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 the location of the drug is unclear. Does the matrix contain the active?

Application/Control Number: 08/945,655

Art Unit: 1617

Applicants argue that the claim language includes a partially enveloped active. However, applicants do not cite language in the specification showing that applicants contemplated such a limitation.

One of ordinary skill cannot clearly determine the metes and bounds of the claimed vehicle.

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on 305-1877. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Application/Control Number: 08/945,655

Art Unit: 1617

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234.

Webman/tgd June 3, 2003

A PART OF THE PROPERTY OF THE PART OF THE